DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
g1285d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

May 23, 2001

Sim Hoffman
Owner
Advanced Professional Imaging Medical Group
585 Knott Avenue
Anaheim, CA 92804

W/L Number: 46 - 01
Inspection ID: 1909830005
FEI: 1000518798

Dear Mr. Hoffman,

We are writing to you because on May 10, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following **REPEAT** Level 2 findings at your facility:

- Level 2: The facility has not specified adequate procedures to be followed for infection control or did not follow them when required.

- Level 2: The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. These problems are identified as Level 2 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the other Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: 1 of 5 random reports reviewed did not contain an acceptable assessment category.

- Level 2: There is no designated audit (reviewing) interpreting physician.

- Level 2: Medical audit and outcome analysis was not performed annually.

- Level 2: Medical audit and outcome analysis was not done separately for each individual.

- Level 2: Medical audit and outcome analysis was not done for the facility as a whole.

- Level 2: Corrective action before further exams (for a failing image score) or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit #1 (a [redacted] machine, model [redacted], serial number [redacted]) which is located in the mobile room.

- Level 2: Corrective action before further exams (for a failing image score) or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit #2 (manufacturer [redacted], serial number [redacted] located in the Sophie Classic room.

- Level 2: Failed to produce documents verifying that the medical physicist, [redacted], (6 CME's in 36 months) met the continuing education requirement of having taught or completed at least fifteen (15) continuing education units in mammography in 36 months.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number 949-798-7708.

Sincerely,

Alonza E. Cruse
District Director

cc:

State of California
Dept. of Health Services
Radiological Health Unit; Region #5
1800 East Lambert; Suite #125
Brea, CA 92821-4370